NEBRASKA HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE

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TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 7 HEALTH CLINICS

Note: In these draft regulations, proposed fee changes are found on pages 14-15. Technical, editing, and writing style changes are made throughout the chapter. Other proposed changes will revise or add regulations on:

- ♦ Definitions, pages 2, 4, 6, and 7
- ♦ Renewal applications, page 10
- ♦ Events requiring notice to the Department, page 12
- ◆ Deemed compliance, pages 13-14
- ♦ Inspections, pages 15, 17, and 19
- ♦ Background checks on unlicensed direct care staff, pages 21-22
- Disaster preparedness, pages 36-37
- ♦ Physical plant standards, pages 41, 44, and 46

<u>7-001 SCOPE AND AUTHORITY:</u> These regulations govern licensure of Health Clinics. The regulations are authorized by and implement the Health Care Facility Licensure Act, <u>Neb. Rev.</u> Stat. <u>Sections</u> §§ 71-401 to 71-462.

<u>7-001.01</u> These regulations apply to any health care facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to:

- 1. An ambulatory surgical center:
- 2. A public health clinic:
- 3. A facility where 10 or more abortions as defined in Neb. Rev. Stat. Section § 28-326 are performed during any one calendar week;
- 4. A facility providing hemodialysis and not licensed as another type of health care facility: or
- 5. A facility providing labor and delivery services and not licensed as another type of health care facility.

7-001.02 Health clinic does not include:

- A health care practitioner facility which is a residence, office or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing Law or any distinct part of such residence, office or clinic unless such facility:
 - a. Is an ambulatory surgical center;
 - b. Performs 10 or more abortions during any one calendar week;
 - c. Provides hemodialysis services; or
 - d. Provides labor and delivery services.

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2. A facility which provides only routine health screenings, health education or immunizations.

7-002 DEFINITIONS

<u>Abuse</u> means any knowing, intentional or negligent act or omission on the part of a person which results in physical, sexual, verbal or mental abuse, unreasonable confinement, cruel punishment, exploitation, or denial of essential care, treatment and services to a patient.

Activities of daily living (See definition of "Care.")

Adjoining means located to allow access without having to enter a general corridor area used or observed by other facility occupants.

<u>Administrator</u> means the operating officer for a health clinic and may include such titles as administrator, chief executive officer, manager, superintendent, director or similar designation.

Ambulatory surgical center means a facility:

- Where surgical services are provide to persons not requiring hospitalization who are admitted to and discharged from such facility within the same working day and are not permitted to stay overnight at such facility;
- 2. Which meets all applicable requirements for licensure as a health clinic under the Health Care Facility Licensure Act; and
- Which has qualified for a written agreement with the Health Care Financing Administration of the United States Department of Health and Human Services or its successor to participate in Medicare as an ambulatory surgical center as defined in 42 CFR 416.1 to 416.200 et seq. or which receives other third-party reimbursement for such services.

Ambulatory surgical center does not include an office or clinic used solely by a practitioner or group of practitioners in the practice of medicine, dentistry, or podiatry.

<u>Applicant</u> means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

<u>Biological</u> means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

<u>Care</u> means the exercise of concern or responsibility for the comfort, welfare, and habilitation of persons, including a minimum amount of supervision and assistance with or the provision of personal care, activities of daily living, health maintenance activities, or other supportive services. For purposes of this chapter:

1. <u>Activities of daily living</u> means transfer, ambulation, exercise, toileting, eating, self-administered medication, and similar activities;

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- Health maintenance activities means noncomplex interventions which can safely be performed according to exact direction, which do not require alteration of the standard procedure, and for which the results and patient responses are predictable; and
- 3. <u>Personal care</u> means bathing, hair care, nail care, shaving, dressing, oral care, and similar activities.

Complaint means an expression of a concern or dissatisfaction.

<u>Completed application</u> means the application that contains all the information specified in 175 NAC 7-003 and includes all required attachments and documentation and the licensure fee.

Department means the Department of Health and Human Services Regulation and Licensure.

<u>Designee</u> means a person who is authorized by law or the patient to act on his or her behalf, for example a parent of a minor child, a legal guardian, a conservator, and an attorney in fact named in a durable power of attorney for health care.

<u>Device</u> means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a medical practitioner and dispensed by a pharmacist or other person authorized by law to do so.

<u>Direction and monitoring</u> means, for the purpose of medication administration, the acceptance of responsibility for observing and taking appropriate action regarding any desired effects, side effects, interactions and contraindications associated with the medication. Direction and monitoring can be done by a:

- Competent individual for himself or herself;
- 2 Caretaker; or
- 3. Licensed health care professional.

<u>Director</u> means the Director of Regulation and Licensure.

Drug means substances as defined in Neb. Rev. Stat. Section § 71-1, 142.

<u>Existing facility</u> means a licensed health care facility or a facility whose construction or remodeling plans were approved by the Department prior to the effective date of 175 NAC 7.

<u>Exploitation</u> means the taking of property of a patient by means of undue influence, breach of a fiduciary relationship, deception, or extortion or by any unlawful means.

Facility means a health clinic as defined.

<u>Five rights</u> means getting the right drug to the right recipient in the right dosage by the right route at the right time.

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Food code means the Nebraska Food Code, Chapters 1-7, 1999 Edition, as defined in Neb. Rev. Stat. § 81-2,244.01 and as published by the Nebraska Department of Agriculture, Bureau of Dairies and Foods, except for compliance and enforcement provisions.

<u>Food service</u> means the storage, preparation, serving, and disposition of food intended for consumption in a health clinic. Food service does not include provision of prepackaged snacks or nutritional supplements.

<u>Foreign</u> when applied to corporations means all those created by authority other than that of the State of Nebraska.

<u>Grievance</u> means a written expression of dissatisfaction which may or may not be the result of an unresolved complaint.

<u>Health care facility</u> means an ambulatory surgical center, an assisted-living facility, a center or group home for the developmentally disabled, a critical access hospital, a general acute hospital, a health clinic, a hospital, an intermediate care facility, an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, a pharmacy, a psychiatric or mental hospital, a public health clinic, a rehabilitation hospital, a skilled nursing facility or a substance abuse treatment center.

<u>Health care practitioner</u> means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

<u>Health care practitioner facility</u> means the residence, office, or clinic of a practitioner or group of practitioners credentialed under the Uniform Licensing law or any distinct part of the residence, office, or clinic.

<u>Health care service</u> means an adult day service, a home health agency, a hospice or hospice service, or a respite care service.

Health maintenance activities (See definition of "Care.")

<u>Health clinic</u> means a facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than twenty-four <u>24</u> consecutive hours to persons not residing or confined at such facility. Health clinic includes, but is not limited to, an ambulatory surgical center or a public health clinic.

Health clinic does not include:

- 1. A health care practitioner facility
 - a. Unless such facility is an ambulatory surgical center;
 - b. Unless ten or more abortions, as defined in subdivision (1) of section Neb. Rev. Stat. § 28-326, are performed during any one calendar week at such facility; or

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- c. Unless hemodialysis or labor and delivery services are provided at such facility; or
- 2. A facility which provides only routine health screenings, health education, or immunizations.

<u>Hemodialysis</u> means the mechanical process of removing unwanted wastes and fluid from the blood to prevent toxic buildup in patients whose kidneys no longer perform this function. This is done by circulating a patient's blood through a semipermeable membrane, or dialyzer. Circulation occurs outside the patient's body.

<u>Licensed health care professional</u> means an individual for whom administration of medication is included in the scope of practice.

<u>Licensee</u> means the individual, government, corporation, partnership, limited liability company, or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

<u>Medical practitioner</u> means any licensed physician, osteopathic physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, certified registered nurse anesthetist, advanced practice registered nurse, or certified nurse midwife.

<u>Medication</u> means any prescription or nonprescription drug intended for treatment or prevention of disease or to affect body function in humans.

Medication administration includes, but is not limited to:

- 1. Providing medications for another person according to the five rights;
- 2. Recording medication provision; and
- 3. Observing, monitoring, reporting and otherwise taking appropriate actions regarding desired effects, side effects, interactions, and contraindications associated with the medication.

<u>Medication aide</u> means an individual who is listed on the medication aide registry operated by the Department as provided in 172 NAC 95 and 96.

<u>Medication provision</u> means the component of the administration of medication that includes giving or applying a dose of a medication to an individual and includes helping an individual in giving or applying such medication to himself or herself.

<u>Mental abuse</u> means humiliation, harassment, threats of punishment, deprivation or other actions causing mental anguish.

NAC means Nebraska Administrative Code.

<u>Neglect</u> means a failure to provide care, treatment or services necessary to avoid physical harm or mental anguish of a patient.

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<u>New construction</u> means a facility or a distinct part of a facility in which care and treatment is to be provided and which is enlarged, remodeled or altered in any fashion or is built from the ground up on or after the effective date of 175 NAC 7.

<u>New facility</u> means a facility or a distinct part of a facility in which care and treatment is to be provided and which is not currently licensed as a health care facility. New facility also includes those facilities, which were previously licensed for care and treatment in another licensure category which now intend to seek licensure in a different category.

<u>Patient</u> means a person who receives care <u>and treatment</u> as recommended by a medical practitioner at a health clinic.

Personal care (See definition of "Care.")

<u>Physical abuse</u> means hitting, slapping, pinching, kicking, or other actions causing injury to the body.

<u>Physician</u> means any person authorized to practice medicine in this state as provided in <u>Neb.</u> <u>Rev. Stat.</u> <u>Sections</u> §§ 71-102 to 71-110.

<u>Premises</u> means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

<u>PRN</u> means an administration scheme in which a medication is not routine, is taken as needed and requires assessment for need and effectiveness.

<u>Public health clinic</u> means the department, and county, city-county, or multicounty health department, or any private not-for-profit family planning clinic licensed as a health clinic.

<u>Qualified inspector</u> means a professional architect or engineer licensed to practice in Nebraska, an official or employee of a local jurisdiction authorized by that jurisdiction to make inspections or particular building equipment or systems, or an individual certified by a nationally recognized organization to make such inspections.

<u>Routine health screenings</u> means the collection of health data through the administration of a screening tool designed for a specific health problem, evaluation, and comparison of results to referral criteria, and referral to appropriate sources of care, if indicated.

<u>Schematic plans</u> means a diagram of the facility or service which describes the number and location of beds; the location of care and treatment rooms, Life Safety Code construction and occupancy classifications locations, fire compartments, and Fire Marshal approved points of safety.

<u>Screening tool</u> means a simple interview or testing procedure to collect basic information on health status.

Sexual abuse means sexual harassment, sexual coercion, or sexual assault.

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<u>Treatment</u> means a therapy, modality, product, device, or other intervention used to maintain well being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition.

Unlicensed direct care staff means personnel who are not licensed, certified, or registered under the Uniform Licensing Law or other state laws governing the practice of health care and whose primary responsibility is to manage, supervise, and/or provide direct care to patients. These include nursing assistants and medication aides.

<u>Verbal abuse</u> means the use of oral, written, or gestured language including disparaging and derogatory terms to patients or within their hearing distance.

<u>7-003 LICENSING REQUIREMENTS AND PROCEDURES:</u> Any person intending to establish, operate, or maintain a health clinic must first obtain a license from the Department. A facility must not hold itself out as a health clinic or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the health clinic meets the care, treatment, operational and physical plant standards contained in 175 NAC 7.

<u>7-003.01 Initial License</u>: The initial license process occurs in two stages. The first stage consists of the applicant's submission of affirmative evidence of the ability to comply with the operational and physical plant standards contained in 175 NAC 7-006 and 7-007. The application is not complete until the Department receives documents specified in 175 NAC 7-003.01.

The second stage consists of the Department's review of the completed application together with an inspection of the health clinic. The Department determines whether or not the applicant for an initial license meets the standards contained in 175 NAC 7 and the Health Care Facility Licensure Act.

<u>7-003.01A Applicant Responsibilities:</u> An applicant for an initial health clinic license must:

- 1. Intend to provide health clinic services as defined;
- 2. Comply with the applicable codes, guidelines, and standards specified in 175 NAC 7-007:
- 3. Submit a written application to the Department as provided in 175 NAC 7-003.01B;
- 4. Receive approval in writing, from the Department, of schematic plan and, if new construction, of construction plans; and
- 5. Notify the Department at least 30 working days prior to planned patient occupancy.

<u>7-003.01B Application Requirements:</u> The applicant may construct an application or obtain an application form from the Department. The application must include:

1. Full name of the health clinic to be licensed, street and mailing address, telephone number and facsimile number, if any;

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- Type of health clinic to be licensed;
- 3. Name of the administrator;
- 4. Name and address(es) of the health clinic owner(s);
- 5. Ownership type;
- 6. Mailing address(es) for the owner(s);
- 7. Preferred mailing address for receipt of official notices from the Department;
- 8. List of names and addresses of all persons in control of the health clinic. The list shall must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the health clinic. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
- Legal name of the individual or business organization (government, corporation, partnership, limited liability company, or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 7;
- 10. Applicant's federal employer identification number, if not an individual;
- 11. Applicant's social security number, if the applicant is an individual (To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document);
- 12. Signature(s) of:
 - a. The owner, if the applicant is an individual or partnership;
 - b. Two of its members, if the applicant is a limited liability company;
 - c. Two of its officers, if the applicant is a corporation; or
 - d. The head of the governmental unit having jurisdiction over the health clinic to be licensed, if the applicant is a governmental unit;
- 13. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
- 14. Schematic plans;
- 15. For new construction, construction plans completed in accordance with the Engineers and Architects Regulation Act, Neb. Rev. Stat. Sections §§ 81-3401 to 81-3455. An applicant may construct a project description and/or certification document, or obtain a form from the Department. Construction plans must include the following:
 - a. Project name, description of the project with quantity and floor area information on bed, care, treatment, and toileting locations, building systems, medical equipment, street address, and contact person;
 - b. Site plan, floor plans, elevations, wall and building sections, construction details, plumbing and electrical diagrams, construction component schedules;

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- c. Complete list of names, titles, and telephone numbers of other authorities reviewing or inspecting the construction;
- d. Upon Department request, any additional information that may be required for review, such as structural and mechanical calculations, electrical system calculations, and product and equipment information; and
- e. Certification, if any, from a licensed architect or engineer that the schematic plans, construction plans, and any revisions thereof meet the requirements of 175 NAC 7-007;
- 16. Planned occupancy date;
- 17. Copies of zoning approval from the relevant jurisdiction;
- 18. Occupancy certificates issued by the State Fire Marshal or delegated authority; and
- 19. Required licensure fee specified in 175 NAC 7-004.09.

7-003.01C Department Responsibilities: The Department must will:

- 1. Review the application for completeness;
- 2. Provide notification to the applicant of any information needed to complete the application;
- Confirm, either by Department review or by accepting certification from an architect or engineer, that the schematic plans and, if new construction, the construction plans meet the standards of 175 NAC 7-007;
- 4. Upon receipt of the requested information, conduct an on-site inspection in accordance with 175 NAC 7-005 prior to the issuance of a health clinic license; and
- 5. Issue or deny a license based on the results of the initial inspection.

<u>7-003.01D</u> <u>Denial of License:</u> See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's denial of an initial license.

7-003.02 Renewal Licenses

<u>7-003.02A</u> <u>Licensee Responsibilities:</u> The licensee must submit a written application to the Department. The licensee may construct an application, or obtain an application form from the Department. The application must include:

- 1. Full name of the health clinic to be licensed, street and mailing address, telephone number, and facsimile number, if any;
- 2. Type of health clinic to be licensed;
- 3. Name of the administrator;
- 4. Name and address(es) of the health clinic or service owner(s);
- 5. Ownership type;
- 6. Mailing address(es) for the owner(s):
- 7. Preferred mailing address for receipt of official notices from the Department;

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- 8. List of names and addresses of all persons in control of the health clinic. The list shall must include all individual owners, partners, limited liability company members, parent companies, if any, and members of boards of directors owning or managing the operations and any other persons with financial interests or investments in the health clinic. In the case of publicly held corporations, the individual owners listed must include any stockholders who own 5% or more of the company's stock;
- Legal name of the individual or business organization (government, corporation, partnership, limited liability company or other type) to whom the license should be issued and a statement that the individual or organization accepts the legal responsibility for compliance with 175 NAC 7;
- 10. Applicant's federal employer identification number, if an individual;
- 11. Applicant's social security number if the applicant is an individual. To ensure social security numbers are not part of public records and are used only for administrative purposes, applicants may submit social security numbers in a separate document;
- 12. Number of patient admissions in the past year;
- 13. Signature(s) of:
 - a. The owner, if the applicant is an individual or partnership;
 - b. Two of its members, if the applicant is a limited liability company;
 - c. Two of its officers, if the applicant is a corporation; or
 - d. The head of the governmental unit having jurisdiction over the health clinic to be licensed, if the applicant is a governmental unit;
- 14. Copy of the registration as a foreign corporation filed with the Nebraska Secretary of State, if applicant is a foreign corporation;
- 154. Occupancy certificates issued by the State Fire Marshal or delegated authority dated within the 12 18 months prior to the license expiration date; and
- 165. Required licensure fee as specified in 175 NAC 7-004.09.

7-003.02B Department Responsibilities: The Department must will:

- 1. Send a notice of expiration and an application for renewal to the licensee's preferred mailing address not later than 30 days prior to the expiration date. The licensure renewal notice specifies:
 - a. Date of expiration;
 - b. Fee for renewal:
 - c. License number; and
 - d. Name and address of the health clinic.
- 2. Issue a renewal when it determines that the licensee has submitted a completed application;
- 3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

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- a. The licensee failed to pay the renewal fee or submit an application or both;
- b. The license has expired;
- c. The Department will suspend action for 30 days following the date of expiration:
- d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
- e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.
- Place the health clinic license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the health clinic may not operate. The license remains in lapsed status until it is reinstated.

<u>7-003.02C</u> Refusal to Renew: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's refusal to renew a license.

<u>7-003.03</u> Reinstatement from Lapsed Status: A health clinic requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required licensure fee specified in 175 NAC 7-004.09. The application must conform to the requirements specified in 175 NAC 7-003.02.

<u>7-003.03A</u> The Department must will review the application for completeness and must will decide if an onsite inspection is needed to determine compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 7-006 and 7-007. The decision is based on the following factors:

- 1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
- 2. Whether the health clinic has provided care or treatment from the site under a license that is different from the lapsed license.

<u>7-003.03B</u> When the Department decides that a reinstatement inspection is warranted, it <u>must will</u> conduct the inspection in accordance with 175 NAC 7-005.

<u>7-003.03C</u> When the Department decides that a reinstatement inspection is not warranted, it <u>must will</u> reinstate the license.

<u>7-003.03D</u> Refusal to Reinstate: See 175 NAC 7-008.01 and 7-008.02 for grounds and procedures for the Department's refusal to reinstate a lapsed license.

7-004 GENERAL REQUIREMENTS

<u>7-004.01 Separate License:</u> An applicant must obtain a separate license for each type of health care facility or health care service that the applicant seeks to operate. All buildings

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in which care and treatment is provided must comply with 175 NAC 7-006 and 7-007. A single license may be issued for:

- 1. A health clinic operating in separate buildings or structures on the same premises under one management;
- 2. An inpatient facility that provides services on an outpatient basis at multiple locations; or
- 3. A health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area served by the health clinic and sharing administration with the clinics.

<u>7-004.02 Single License Document:</u> The Department may issue one license document that indicates the various types of health care facilities or health care services for which the entity is licensed.

<u>7-004.03 Effective Date and Term of License:</u> A health clinic license expires on the last day of February each year.

<u>7-004.04 License Not Transferable:</u> A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the health clinic remains on the same premises, the inspection in 175 NAC 7-005 is not required. If there is a change of premises, the health clinic must pass the inspection specified in 175 NAC 7-005.

<u>7-004.05</u> Change of Ownership or <u>Premises Location</u>: The licensee must notify the Department in writing <u>30 days before</u> within five working days when a health clinic is sold, leased, discontinued, or moved to a new premises location.

<u>7-004.06 Notification:</u> An applicant or licensee must notify the Department <u>in writing by electronic mail, facsimile, or postal service</u>:

- 1. To request a single license document;
- 2. To request simultaneous facility or service licensure inspections for all types of licensure held or sought; er
- 3. If new construction is planned, and submit construction plans for Department approval prior to any new construction affecting patient care and treatment areas of the health clinic. The Department may accept certification from an architect or engineer in lieu of Department review-:
- 4. Within 24 hours if a facility has reason to believe that a patient death was due to abuse or neglect by staff;
- Within 24 hours of an accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients; or
- 6. Within 24 hours of all clinic fires.

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<u>7-004.07 Information Available to Public:</u> The licensee must make available for public inspection upon request licenses, license record information, and inspection reports. This information may be displayed on the licensed premises.

7-004.08 Deemed Compliance

<u>7-004.08A</u> Accreditation or Certification: The Department must may deem an applicants or licensees in compliance with 175 NAC 7-006 based on its accreditation or certification as a health clinic, ambulatory surgical center, provider of hemodialysis services, or provider of labor and delivery services by the:

- Accredited as an Ambulatory Surgical Center or End Stage Renal Dialysis facility by the Joint Commission on Accreditation of Healthcare Organizations;
- 2. Accredited as an Ambulatory Surgical Center by the Accreditation Association of Ambulatory Health Care; or
- 3. Certified to participate in the Medicare or Medicaid certification program.

<u>7-004.08A1</u> An Aapplicants or licensees must request the Department to deem its facility in compliance with 175 NAC 7-006 based on accreditation or certification. The request must be:

- 1. Made in writing;
- 2. Submitted within 30 days of receipt of a report granting accreditation or certification; and
- 3. Accompanied by a copy of the accreditation or certification report.

7-004.08A2B Upon receipt of the request, the Department must will deem the facility in compliance with 175 NAC 7-006 and must will provide written notification of the decision to the facility within ten working days of receipt of the request.

7-004.08A3 The Department will exclude a facility that has been deemed in compliance with 175 NAC 7-006 from the random selection of up to 25% of facilities for compliance inspections under 175 NAC 7-005.04A. The facility may be selected for a compliance inspection under 175 NAC 7-005.04B.

7-004.08A4C To maintain deemed compliance, the licensee must maintain the accreditation or certification on which the license was issued. If the accreditation or certification has been sanctioned, modified, terminated, or withdrawn, the licensee must notify the Department within 15 days of receipt of notification of the action. After notifying the Department, giving the notice, the health clinic may continue to operate unless the Department determines that the health clinic no longer meets the requirements for licensure under the Health Care Facilities Licensure Act. If the Department determines the facility no longer qualifies for deemed compliance, the facility is subject to inspections under 175 NAC 7-005.

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7-004.08B Food Code: The Department will deem an applicant or licensee to be in compliance with the food service physical environment and equipment portions of the Food Code when:

- The facility is located in a jurisdiction where there is a local health authority that inspects the facility's on-site food service using the Food Code:
- 2. The facility has been issued a certificate or similar document by the local health authority as evidence of compliance with the Food Code; and
- 3. The facility has provided the Department with a copy of the certificate or similar document issued by the local health authority. The document must have been issued within 18 months of the date the Department conducts the licensure inspection.

7-004.08B1 The facility must maintain compliance with the Food Code as evidenced by the Food Code compliance certificate not having been modified or terminated by the issuing local health authority.

7-004.08B2 The facility must notify the Department when the local health authority modifies or terminates the Food Code compliance certificate. The notification must be sent to the Department in writing within 15 days after the facility receives notification from the local health authority of any change.

7-004.08B3 If the facility contracts with an entity to provide food service, the contractor must meet the requirements of the Food Code, and the facility must show proof of such approval to the Department.

7-004.09 Fees: The Department must will charge fees for licensure as set forth below:

7-004.09A Initial Licensure Fee:

1. All types of health clinics except public health clinics and ambulatory surgical centers: \$500 \\$600

2. Public health clinics: \$250 \$400

3. Ambulatory surgical centers:

a. 1 operating/procedure room
b. 2 to 3 operating/procedure rooms
c. 4 or more operating/procedure rooms
\$450 \\
\$1,250 \\
\$1,350 \\
\$1,450

7-004.09B Renewal Licensure Fees:

1. All types of health clinics except public health clinics and ambulatory surgical centers:

a.	1 to 50 patient admissions in the past year	\$500
b.	51 to 100 patient admissions in the past year	\$525 <u>\$800</u>
C.	101 or more patient admissions in the past year	\$550 \$1,000

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Public health clinics: 2.

a.	1 to 50 patient admissions in the past year	\$250
b.	51 to 100 patient admissions in the past year	\$275 \$450
C.	101 or more patient admissions in the past year	\$300 <u>\$500</u>

3. Ambulatory surgical centers:

a.	1 operating/procedure room	\$450 \$1,250
b.	2 to 3 operating/procedure rooms	\$500 \$1,350
C.	4 or more operating/procedure rooms	\$550 \$1,450
d.	All ambulatory surgical centers must also pa	ay an additional fee
	under the Outpatient Surgical Procedures D	ata Act, Neb. Rev.
	Stat. §§ 81-6,111 to 81-6,119, as follows:	

<u>(1)</u>	500 or fewer surgeries per year	\$27 <u>5</u>
(2)	501 to 2,000 surgeries per year	\$350
(3)	More than 2,000 surgeries per year	\$425

<u>7-004.09C</u> Duplicate original license:

\$ 10

7-004.09D Refunds for denied applications:

- If the Department did not perform an inspection, the license fee is 1. refunded except for an administrative fee of \$25: or
- 2. If the Department performed an inspection, the fee is not refunded.

7-005 INSPECTIONS: To determine compliance with operational, care, treatment, and physical plant standards, the Department inspects the health clinic prior to and following licensure. The Department determines compliance through on-site inspections, review of schematic and construction plans, and reports of qualified inspectors. Re-inspections are conducted by on-site inspection or review of documentation requested by the Department.

7-005.01 Initial Inspection: The Department must will conduct an announced initial onsite inspection to determine compliance with 175 NAC 7-006 and 7-007. The inspection must will occur within 30 working days, or later if requested by the applicant, of receipt of a completed application for an initial license. The Department must will provide a copy of the inspection report to the health clinic within ten working days after completion of an inspection.

7-005.02 Results of Initial Inspection

7-005.02A When the Department finds that the applicant fully complies with the requirements of 175 NAC 7-006 and 7-007, the Department must will issue a license.

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<u>7-005.02B</u> When the Department finds that the applicant had complied substantially but has failed to comply fully with the requirements of 175 NAC 7-006 and 7-007 and the failure(s) would not pose an imminent danger of death or physical harm to persons served by the health clinic, the Department may issue a provisional license. The provisional license:

- 1. Is valid for up to one year; and
- 2. Is not renewable.

<u>7-005.02C</u> When the Department finds the applicant has one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse relationship to the health, safety, or security of the persons served by the health clinic, the Department may send a letter to the health clinic requesting a statement of compliance. The letter must will include:

- 1. A description of each violation;
- 2. A request that the health clinic submit a statement of compliance within ten working days; and
- 3. A notice that the Department may take further steps if the statement of compliance is not submitted.

<u>7-005.02D</u> The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department <u>must will</u> take one of the following actions:

- 1. If the health clinic submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department must will issue either a regular license or a provisional license; or
- 2. If the health clinic fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may deny the license.

<u>7-005.02E</u> When the Department finds the applicant fails to meet the requirements of 175 NAC 7-006 and 7-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department must will deny the license.

<u>7-005.03 Physical Plant Inspections:</u> The Department must will conduct inspections for conformity with construction plans and compliance with 175 NAC 7-007 at new facilities or new construction prior to use or occupancy.

<u>7-005.03A</u> On-site progress inspections of the physical plant by qualified inspectors for conformity to construction documents and compliance with code requirements may occur at any time after construction has begun and prior to the concealment of essential components.

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<u>7-005.03B</u> The Department must will conduct an on-site final inspection of the physical plant prior to use or occupancy. In lieu of an on-site final inspection by the Department, the Department may accept a certification from a licensed architect or engineer that the physical plant meets the requirements of the Health Care Facility Licensure Act and 175 NAC 7, and that the health clinic is complete and ready for occupancy in accordance with Department-approved plans. The architect or engineer may construct a certification form or obtain a certification form from the Department.

7-005.03B1 The certification must state:

- 1. Name of the architect or engineer;
- 2. Name of the professional entity with which he or she is affiliated, if any;
- 3. Address and telephone number;
- 4. Type of license held, the state in which it is held, and the license number:
- 5. Name and location of the health clinic;
- 6. Name(s) of the owner(s) of the health clinic;
- 7 New construction had the building structure and plumbing rough-in inspected by a qualified inspector prior to the time these would be concealed and preclude observation;
- 8. All new construction, care and treatment room sizes, handrails, grab bars, hardware, building systems, protective shielding, privacy curtains, appropriate room finishes, and other safety equipment are completed in accordance with approved construction plans; and
- 9. The facility is furnished, cleaned, and equipped for the care and treatment to be performed in compliance with 175 NAC 7-007, and approved for use and occupancy.

7-005.03B2 The certification must have attached to it:

- Copies of documents from other authorities having jurisdiction verifying that the facility meets the codes specified in 175 NAC 7-007.03A, and approved for use and occupancy;
- 2. Copies of certifications and documentation from equipment and building system installers verifying that all equipment and systems installed are operating and approved for use and occupancy; and
- 3. Schematic floor plans documenting actual room numbers and titles, bed locations, and life safety information.

<u>7-005.04 Timing of Compliance Inspections</u>: The Department may, following the initial <u>licensure of a health clinic</u>, conduct an <u>unannounced</u> onsite inspection at any time as it deems necessary to determine compliance with 175 NAC 7-006 and 7-007. The inspection may occur based on random selection or focused selection.

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<u>7-005.04A Random Selection:</u> Each year the Department may inspect up to 25% of the health clinics based on a random selection of licensed health clinics.

<u>7-005.04B Focused Selection:</u> The Department may inspect a health clinic when the Department is informed of one or more of the following:

- 1. An occurrence resulting in patient death or serious physical harm;
- 2. An occurrence resulting in imminent danger to or the possibility of death or serious physical harm to patients;
- An accident or natural disaster resulting in damage to the physical plant and having a direct or immediate adverse effect on the health, safety, and security of patients;
- 4. The passage of five years without an inspection;
- 5. A complaint alleging violation of the Health Care Facility Licensure Act or 175 NAC 7;
- 6. Complaints that, because of their number, frequency, or type, raise concerns about the maintenance, operation, or management of the health clinic:
- 7. Financial instability of the licensee or of the licensee's parent company;
- 8. Outbreaks or recurrent incidents of physical health problems such as dehydration, pressure sores, or other illnesses;
- 9. Change of services, management, or ownership;
- 10. Change of status of accreditation or certification on which licensure is based as provided in 175 NAC 7-004.08; or
- 11. Any other event that raises concerns about the maintenance, operation, or management of the health clinic.

7-005.05 Results of Compliance Inspections

<u>7-005.05A</u> When the inspection reveals violations that create imminent danger of death or serious physical harm or have a direct or immediate adverse effect on the health, safety, or security of persons served by the health clinic, the Department must will review the inspection findings within 20 working days after the inspection. If the evidence from the inspection supports the findings, the Department must-will impose discipline in accordance with 175 NAC 7-008.03.

<u>7-005.05B</u> When the inspection reveals one or more violations that create no imminent danger of death or serious physical harm and no direct or immediate adverse effect on the health, safety, or security of persons served by the health clinic, the Department may request a statement of compliance from the health clinic. The statement of compliance must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the health clinic submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department must will not take any disciplinary action against the license; or

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2. If the health clinic fails to submit and implement a statement of compliance, the Department must will initiate disciplinary action against the health clinic license, in accordance with 175 NAC 7-008.

7-005.06 Re-inspections

<u>7-005.06A</u> The Department may conduct re-inspections to determine if a health clinic fully complies with the requirements of 175 NAC 7-006 and 7-007. The re-inspection must occur within 90 days of the first inspection, or sooner as requested by the licensee. The re-inspection may occur after the Department: Re-inspection may consist of an on-site inspection or a review of documentation requested by the Department. Re-inspection occurs:

- 1. After the Department has issued a provisional license;
- 2. Before a provisional license is converted to a regular license;
- 3. After the Department has imposed disciplinary action;
- 4. Before a disciplinary action is modified or terminated; or
- 5. After the Department receives a statement of compliance for cited violations.
- 1. Receives a statement of compliance;
- 2. Has imposed disciplinary action; or
- 3. Has issued a provisional license.

7-005.06B Following a re-inspection, the Department may:

- 1. Convert a provisional license to a regular license;
- 2. Affirm that the provisional license is to remain effective: or
- 3. Modify a disciplinary action in accordance with 175 NAC 7-008.02-; or
- 4. Grant full reinstatement of the license.

7-006 STANDARDS OF OPERATION, CARE AND TREATMENT: 175 NAC 7-006 applies to the following types of health clinics unless specified otherwise: public health clinics, ambulatory surgical centers, facilities at which ten or more abortions are performed during any one calendar week, facilities providing hemodialysis, and facilities providing labor and delivery services. Each health clinic must organize, manage, and administer in a manner consistent with the size, resources, and type of services to assure each patient receives the necessary care and treatment.

<u>7-006.01 Licensee Responsibilities:</u> The licensee of each health clinic must assume the responsibility for the total operation of the facility. The licensee responsibilities include:

- 1. Monitoring policies to assure the appropriate administration and management of the health clinic;
- 2. Maintaining the health clinic's compliance with all applicable state statutes and relevant rules and regulations;

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- 3. Providing quality care and treatment to patients whether care and treatment are furnished by health clinic staff or through a contract with the health clinic:
- 4. Periodically reviewing reports and recommendations regarding the Quality Assurance/Performance Improvement program and implementing programs and policies to maintain and improve the quality of patient care and treatment;
- 5. Maintaining written minutes of meetings and actions;
- 6. Designating an administrator who is responsible for the day to day management of the health clinic and defining the duties and responsibilities of the administrator in writing;
- 7. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be responsible for the position until another administrator is appointed;
- 8. Notifying the Department in writing within five working days when the vacancy is filled including effective date and name of person appointed administrator; and
- 9. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the health clinic.

<u>7-006.02</u> Administration: The administrator is responsible for planning, organizing, and directing the day to day operation of the health clinic. The administrator must report in all matters related to the maintenance, operation and management of the health clinic and be directly responsible to the licensee or to the person or persons delegated governing authority by the licensee. The administrator's responsibilities include:

- 1. Being on the premises a sufficient number of hours to permit adequate attention to the management of the health clinic;
- 2. Providing for the protection and promotion of patients' health, safety, and well-being:
- 3. Maintaining staff appropriate to meet patient needs;
- 4. Designating a substitute, who is responsible and accountable for management of the health clinic, to act in the absence of the administrator; and
- 5. Developing procedures which require the reporting of any evidence of abuse, neglect or exploitation of any patient served by the health clinic in accordance with Neb. Rev. Stat. Section § 28-372 of the Adult Protective Services Act or in the case of a child, in accordance with Neb. Rev. Stat. Section § 28-711.
- 6. Determining the supervision of and training for emergency medical technician-intermediates or emergency medical technician-paramedics.

<u>7-006.03 Staff Requirements:</u> Each health clinic must maintain a sufficient number of staff with the qualifications, training, and skills to meet operational and patient needs. Each health clinic shall <u>must</u> have job descriptions for each staff position, which include minimum qualifications required for the position.

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<u>7-006.03A Employment Eligibility:</u> Each health clinic must ensure and maintain evidence of the following:

7-006.03A1 Staff Credentials: Each health clinic must verify:

- The current active licensure, registration, certification or other credentials in accordance with applicable state law, prior to staff assuming job responsibilities and must have procedures for verifying that the current status is maintained; and
- 2. That an emergency medical technician-intermediate or an emergency medical technician-paramedic providing service in the health clinic is employed by or serving as a volunteer member of an emergency medical service licensed by the Department.

<u>7-006.03A1a</u> If unlicensed staff assist in provision of care or treatment, such staff should <u>must</u> be supervised by the appropriate licensed health care professional.

<u>7-006.03A2 Health Status:</u> Each health clinic must establish and implement policies and procedures related to the health status of staff to prevent the transmission of disease to patients.

<u>7-006.03A2a</u> Each health clinic must complete a health history screening for all staff prior to assuming job responsibilities and must require staff to have a physical examination when the results of the health history screening indicate the examination is necessary.

7-006.03A3 Criminal Background and Registry Checks: Each health clinic must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.

7-006.03A3a Criminal Background Checks: The health clinic must complete a criminal background check through a governmental law enforcement agency or a private entity that maintains criminal background information.

7-006.03A3b Registry Checks: The health clinic must check for adverse findings on each of the following registries:

- Nurse Aide Registry;
- 2. Adult Protective Services Central Registry;
- 3. Central Register of Child Protection Cases; and
- 4. Nebraska State Patrol Sex Offender Registry.

7-006.03A3c The health clinic must:

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- Determine how to use the criminal background and registry information, except for the Nurse Aide Registry, in making hiring decisions;
- 2. Decide whether employment can begin prior to receiving the criminal background information; and
- 3. Document any decision to hire a person with a criminal background or adverse registry findings, except for the Nurse Aide Registry. The documentation must include how the decision was made and how the facility plans to reduce risk to patients and provide protection, as necessary.

7-006.03A3d The health clinic must not employ a person with adverse findings on the Nurse Aide Registry regarding patient abuse, neglect, or misappropriation of patient property.

<u>7-006.03B Training:</u> Each health clinic must ensure staff receive training in order to perform job responsibilities.

<u>7-006.03B1 Orientation:</u> Each health clinic must provide and maintain evidence of an orientation program for all new staff and, as needed, for existing staff who are given new assignments. The orientation program must include an explanation of the:

- 1. Job duties and responsibilities;
- 2. The health clinic's sanitation and infection control program;
- 3. Organizational structure;
- 4. Patient Rights;
- 5. Patient care policies and procedures;
- 6. Personnel policies and procedures:
- 7. Emergency procedures;
- 8. Disaster preparedness plan; and
- 9. Reporting requirements for abuse, neglect and exploitation in accordance with the Adult Protective Services Act, Neb. Rev. Stat. Section § 28-372 or in the case of a child in accordance with Neb. Rev. Stat. Section § 28-711 and with health clinic policies and procedures.

<u>7-006.03B1a</u> Each health clinic that approves emergency medical technician-intermediates and emergency medical technician-paramedics to provide service as either an employee or a volunteer must provide orientation to registered nurses, physicians, and physician assistants involved in the supervision of emergency medical technician-intermediates and emergency medical technician-paramedics. The orientation must include:

 Information regarding the scope of practice of an emergency medical technician-intermediate or emergency medical technician-paramedic; and

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 Supervision requirements, as determined by the governing authority of the health clinic, for emergency medical technician-intermediates and emergency medical technicianparamedics, to perform activities within their scope of practice as defined in 172 NAC 11, Regulations Governing Out-of-Hospital Emergency Care Providers, Section 11-006.

<u>7-006.03B2</u> Ongoing Training: Each health clinic must maintain evidence of ongoing/continuous inservices or continuing education provided for staff. A record must be maintained including date, topic and participants. Specialized training of staff to permit performance of particular procedures or to provide specialized care, whether as part of a training program or as individualized instruction, must be documented in personnel records.

<u>7-006.03C</u> Employment Record: Each health clinic must maintain a current employment record for each staff person. The record must include information on orientation, inservice, credentialing and health history screening.

<u>7-006.04 Patient Rights:</u> Each health clinic must protect and promote each patient's rights. This includes the establishment of written policies and procedures and enforcement of such to ensure the operations of the clinic afford patients the opportunity to exercise their rights. At a minimum, each patient must have the right to:

- 1. Respectful and safe care by competent personnel;
- 2. Be informed of patient rights during the admission process;
- 3. Be informed in advance about care and treatment and related risks;
- 4. Make informed decisions regarding care and treatment and to receive information necessary to make those decisions;
- 5. Refuse care and treatment and to be informed of the medical consequences of refusing such:
- 6. Formulate advance directives and to have the health clinic comply with the directives unless the clinic notifies the patient of the inability to do so;
- 7. Personal privacy and confidentiality of medical records;
- 8. Be free from abuse, neglect and exploitation;
- Access information contained in his/her medical record within a reasonable time when requested;
- Receive health clinic services without discrimination based upon race, color, religion, gender, national origin, or payer. Health clinics are not required to provide uncompensated or free care and treatment unless otherwise required by law: and
- 11. Voice complaints and grievances without discrimination or reprisal and have those complaints and grievances addressed.

<u>7-006.04A Grievances</u>: Each health clinic must establish and implement a process that promptly addresses grievances filed by patients or their designee. The process, includes, but is not limited to:

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- 1. A procedure for submission of grievances that is made available to patients or representatives;
- 2. Time frames and procedures for review of grievances and provision of a response; and
- 3. How information from grievances and responses are utilized to improve the quality of patient care and treatment.

<u>7-006.05 Quality Assurance/Performance Improvement:</u> Each health clinic must have an effective quality assurance/performance improvement program to evaluate care and treatment provided to patients. The program includes, but is not limited to:

- 1. A written plan of implementation;
- 2. Evaluation of care and treatment provided both by staff and through contract;
- 3. For ambulatory surgical centers, the tracking of surgical procedures that result in unplanned patient admissions to a hospital within 72 hours of a procedure, due to post surgical complications;
- 4. Appropriate action to address problems found through the program;
- 5. Evaluation of the outcome of any action taken; and
- 6. Reporting to the governing authority.

<u>7-006.06 Patient Care and Treatment:</u> Each health clinic must establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with prevailing professional standards, delineate the scope of services provided in the health clinic and encompass aspects to protect the health and safety of patients.

<u>7-006.06A</u> Administration of Medications: Each health clinic must establish and implement policies and procedures to ensure patients receive medications only as legally prescribed by a medical practitioner in accordance with the Five Rights and prevailing professional standards.

<u>7-006.06A1 Methods of Administration of Medications:</u> When the health clinic is responsible for the administration of medications, it must be accomplished by the following methods:

<u>7-006.06A1a Self Administration:</u> The health clinic must allow patients of the health clinic to self-administer medications, with or without supervision, when assessment determines the patient is capable of doing so.

<u>7-006.06A1b</u> <u>Licensed Health Care Professional:</u> When the health clinic utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the health clinic must ensure the medications are properly administered in accordance with prevailing professional standards.

7-006.06A1c Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the health clinic utilizes

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persons other than a licensed health care professional in the provision of medications, the health clinic must follow 172 NAC 95 Regulations Governing the Provision of Medications by Medication Aides and Other Unlicensed Persons and 172 NAC 96 Regulations Governing the Medication Aide Registry. Each health clinic must establish and implement policies and procedures:

- 1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004.
- To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005.
- That specify how direction and monitoring will occur when the health clinic allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:
 - a. Provide routine medication; and
 - b. Provision of medications by the following routes:
 - Oral, which includes any medication given by mouth including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
 - (2) Inhalation which includes inhalers and nebulizers, including oxygen given by inhalation:
 - (3) Topical application of sprays, creams, ointments, and lotions, and transdermal patches; and
 - (4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose.
- 4. That specify how direction and monitoring will occur when the health clinic allows medication aides to perform the additional activities authorized by 172 NAC 95-009, which include but are not limited to:
 - a. Provision of PRN medications:

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- b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or
- c. Participation in monitoring.
- 5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision.
- 6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009.
- 7. That specify how records of medication provision by medication aides will be recorded and maintained.
- 8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:
 - Made to the identified person responsible for direction and monitoring;
 - b. Made immediately upon discovery; and
 - c. Documented in patient medical records.

<u>7-006.06A2</u> Each health clinic must establish and implement policies and procedures for reporting any errors in administration or provision of prescribed medications to the prescriber in a timely manner upon discovery and a written report of the error must be prepared and maintained.

<u>7-006.06A3</u> Each health clinic must establish and implement policies and procedures for reporting any adverse reaction to a medication, in a timely manner upon discovery, to the prescriber and for documenting such event in the patient's medical record.

<u>7-006.06A4</u> Each health clinic must establish and implement procedures to ensure patients receive medications as prescribed by a medical practitioner. At a minimum, the following must be evident:

- 1. A current policy and procedure manual regarding the handling of medications in the health clinic:
- A count of all controlled substances in the health clinic every 24 hours; and
- 3. Only authorized personnel designated by health clinic policy are allowed access to medications.

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<u>7-006.06B Verbal Orders:</u> Each health clinic must establish and implement appropriate policies and procedures for those staff authorized to receive telephone and verbal diagnostic and therapeutic orders.

<u>7-006.06C</u> Patient Education: Each health clinic must establish and implement a process to ensure patients and/or their designee receive appropriate education and instruction to assist in understanding the identified condition and the necessary care and treatment. Any instructions at the time of discharge must be given in writing.

<u>7-006.06D</u> Patient Transfers: Each health clinic must transfer to a health care facility and have procedures for continued care of any patient whose condition does not allow dismissal within 24 hours.

<u>7-006.07 Record Keeping Requirements:</u> Each health clinic must maintain records and reports in such a manner to ensure accuracy and easy retrieval.

<u>7-006.07A</u> Medical Records: Every patient who receives care or treatment in a health clinic must have a medical record established. Medical records must contain sufficient information to clearly identify the patient and document the diagnosis, care, treatment, and results accurately.

<u>7-006.07A1 Content:</u> Medical records must contain, when applicable, the following information:

- 1. Identification data;
- 2. Chief complaint;
- Medical history:
- 4. Physical examination;
- 5. All pathology/laboratory and radiology reports;
- 6. Properly executed informed consent forms:
- 7. Consultation reports;
- 8. Medical practitioner orders;
- 9. Care and treatment provided;
- 10. Progress notes;
- 11. Pertinent observations and events; and
- 12. Instructions to patients, including discharge/dismissal.

<u>7-006.07A2</u> Medical records must contain entries which are dated, legible, and <u>indelible</u> indelibly verified. The author of each entry must be identified and authenticated. Authentication must include signature, written initials, or computer entry.

<u>7-006.07A3</u> Retention: Each health clinic must maintain and preserve all medical records in original, microfilm, electronic, or other similar form, for a period of at least five years. In the case of a minor, the medical records must be kept until three years after the age of majority has been attained. When a health clinic ceases operation, all medical records must be transferred as directed by the patient or authorized representative to the licensed health care

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facility or health care service to which the patient is transferred. All other medical records that have not reached the required time for destruction must be stored to assure confidentiality and the Department must be notified of the address where stored.

<u>7-006.07A4</u> Confidentiality: Medical records must be kept confidential, available only for use by authorized persons or as otherwise permitted by law. Records must be available for examination by authorized representatives of the Department.

<u>7-006.07A5 Access</u>: Patient information and/or records will be released only with consent of the patient or designee or as required by law.

<u>7-006.07A6 Destruction:</u> Medical records may be destroyed only when they are in excess of five years of age. In order to ensure confidentiality, each health clinic must destroy or dispose of medical records by shredding, incineration, electronic deletion, or another equally effective protective measure.

<u>7-006.07B</u> Other Records/Reports: In addition to patient medical records, each health clinic must maintain accurate and complete administrative records of the clinic operation for not less than three years unless longer is required by law.

<u>7-006.07B1</u> A report that summarizes the scope and volume of services provided at the health clinic each year must be maintained.

<u>7-006.08 Infection Control:</u> Each health clinic must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

<u>7-006.08A</u> The infection control program must include, but is not limited to:

- 1. The responsible person(s) for the program;
- 2. A system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and staff:
- 3. A definition of nosocomial infection:
- 4. A system for reporting known or suspected cases of infection acquired at the health clinic among patients and for maintaining records of such infection:
- 5. Maintenance of a record of infection, communicable disease and nosocomial infections:
- 6. Implementation of corrective action plans; and
- 7. Mechanism for evaluation of the program.

<u>7-006.08A</u> Equipment and Supplies: Each health clinic must establish and implement written policies and procedures for cleaning, sterilization and storage of

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supplies and equipment. Equipment and supplies must be maintained in accordance with prevailing professional standards to protect patients from infection.

<u>7-006.08B Handwashing:</u> Facilities for handwashing must be easily accessible and good handwashing techniques must be practiced by staff before and after patient contact.

<u>7-006.08C Food Service:</u> Each health clinic that provides food service must store, prepare, protect, and dispose of food in a safe and sanitary manner and in accordance with the Food Code.

<u>7-006.09 Pharmacotherapy Services:</u> Each health clinic that provides pharmacotherapy services to meet patient needs must maintain drugs, devices, and biologicals under the supervision of a licensed Nebraska pharmacist or licensed Nebraska physician. The storage, control, handling, compounding, administration, provision, and dispensing of drugs, devices, and biologicals must be in accordance with state and federal law.

Any health clinic that conducts a pharmacy or engages in the practice of pharmacy must do so in accordance with Neb. Rev. Stat. Sections §§ 71-1,142 to 71-1,147.61.

Each health clinic must ensure that information relating to interactions, contraindications, side effects, toxicology, dosage, indications for use, and routes of administration for drugs, devices, and biologicals is available to staff at all times.

<u>7-006.09A</u> Emergency Drugs, Devices, and Biologicals: Emergency drugs, devices, and biologicals, as determined by the need of patients served by each health clinic, must be readily available for use when an emergency occurs.

<u>7-006.09B</u> Prescribing Drugs, Devices, and Biologicals: Each health clinic must establish appropriate policies and procedures for those personnel authorized to receive telephone and verbal orders for drugs, devices, and biologicals. A separate policy and procedure must be required in health clinics where drugs, devices, and biologicals are dispensed to patients. All written orders and prescriptions must be legible as required by 175 NAC 7-006.07A1.

<u>7-006.09C</u> Preparation and Compounding of Drugs, Devices, and Biologicals: A current policy and procedure manual regarding the handling of drugs, devices and biologicals in the health clinic must be available at all times to personnel authorized to administer or provide such. The manual must include information on preparation and must comply with all state and federal law regarding the practice of pharmacy.

<u>7-006.09D</u> Dispensing of Drugs, Devices, and Biologicals: All drugs, devices, and biologicals dispensed from a health clinic must be dispensed by a pharmacist, a physician with a dispensing permit, or in accordance with <u>Neb. Rev. Stat.</u> <u>Sections</u> §§ 71-1,147.39 to 71-1,147.61.

7-006.09E Storage of Drugs, Devices, and Biologicals: All drugs, devices, and biologicals must be stored in secured areas and stored in accordance with the

manufacturer's, distributor's, packager's, or dispensing pharmacist's instructions for temperature, light, humidity, and other storage instructions. Only authorized personnel, designated by policy and procedure of the health clinic as responsible for administration, provision, or dispensing, must have access to drugs, devices, and biologicals. The supply of drugs, devices, and biologicals must be protected and restricted to use for legally authorized purposes and must be checked on a regular basis to ensure expired, mislabeled, unlabeled, or unusable products are not available for patient use.

<u>7-006.09F</u> Record Keeping: All drugs, devices, and biologicals administered, provided, or dispensed for a patient must be recorded in the patient's medical record. The record must specify the name, dosage, date, time, and route of administration or provision and identification of the person who administered or provided such.

<u>7-006.09F1</u> A complete and accurate record of all drugs, devices, and biologicals received, stored, administered, provided, dispensed, or disposed of by the health clinic must be kept and maintained for not less than five years.

<u>7-006.09F2</u> Each health clinic must have a policy and procedure for the reporting and recording of any abuse or loss of drugs, devices, and biologicals. Such policy must be in accordance with state and federal law concerning abuse and loss of drugs, devices, and biologicals.

<u>7-006.09G Sample Drugs, Devices, and Biologicals: Personnel of a health clinic must not receive</u> No manufacturer, distributor, or packager samples shall be received by any personnel of a health clinic in violation of any state or federal law.

<u>7-006.09G1</u> A complete and accurate record of all drugs, devices, and biologicals samples received, stored, administered, provided, dispensed, or disposed of by the health clinic must be kept and maintained for not less than five years.

<u>7-006.09G2</u> All samples administered, provided, or dispensed to a patient must be recorded in the patient's medical record.

<u>7-006.09H Investigational Drugs, Devices, and Biologicals:</u> All drugs, devices, and biologicals being used as a part of a clinical investigation must be maintained in a locked and separate area from all other drugs, devices, and biologicals. All investigational drugs, devices, and biologicals should be administered only in accordance with the clinical study protocol.

<u>7-006.09I</u> Disposal of Drugs, Devices, and Biologicals: Each health clinic must ensure that expired, mislabeled, unlabeled, or unusable drugs, devices, and biologicals are not available for patient use and are disposed of in accordance with clinic policies and state and federal law. The disposal must be conducted on a routine basis to prevent storage of large quantities of expired, mislabeled, unlabeled, or unusable drugs, devices, and biologicals.

<u>7-006.10 Laboratory Services:</u> All laboratory testing, whether provided directly by the health clinic or through agreement, must comply with the Clinical Laboratory Improvement Amendments of 1988 as amended (CLIA).

<u>7-006.10A</u> Complete laboratory test result reports must be kept in patient medical records.

<u>7-006.11 Radiology Services:</u> Each health clinic that provides radiology services must be under the direction of a physician and must comply with the provisions of the <u>Neb. Rev. Stat.</u> <u>Sections</u> §§ 71-3501 to 71-3520, Radiation Control Act and the regulations promulgated thereafter.

<u>7-006.11A</u> Personnel performing medical radiography procedures must be licensed in accordance with <u>Neb. Rev. Stat.</u> <u>Sections</u> §§ 71-3515.01 to 71-3515.02, Radiation Control Act and the regulations promulgated thereunder.

<u>7-006.12</u> Ambulatory Surgical Center: Each ambulatory surgical center must meet the regulations specified in 175 NAC 7-006.01 to 7-006.09 and 7-006.15. In addition, each ambulatory surgical center must meet all requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare as an ambulatory surgical center as defined in 42 CFR 416.1 to 416.200 et seq. attached to these regulations and incorporated by this reference.

<u>7-006.12A</u> Each ambulatory surgical center is limited to performing surgical and other medical procedures that can be safely performed in a dedicated operating room or suite and which may require a postoperative recovery room for convalescent stay. An ambulatory surgical center can only provide surgical services to persons who are admitted to and discharged from the ambulatory surgery center within the same working day and must not retain patients past midnight of the day of admission.

<u>7-006.12B</u> Each ambulatory surgical center must maintain a chronological permanent admission and discharge record that, at a minimum, includes:

- 1. Full name of each patient:
- 2. Identification number assigned by the ambulatory surgical center;
- 3. Date and time of admission and discharge:
- 4. Surgical procedure(s) performed;
- 5. Inclusive time of surgical procedure(s);
- 6. Name of surgeon and any assistants(s);
- 7. Name of nursing personnel (scrubbing and circulating);
- 8. Type of anesthesia; and
- 9. Name and title of person administering anesthesia.

<u>7-006.12C</u> Each ambulatory surgical center must provide discharge planning to patients or their designee.

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<u>7-006.12C1</u> If a patient is discharged to a health care facility or health care service, necessary medical information must be transferred to the receiving facility or service.

<u>7-006.12D</u> Before discharge from the ambulatory surgical center, the patient must be evaluated for proper recovery. Qualified personnel must remain with the patient until the patient's status is stable and protective reflexes have returned to normal. A patient may be discharged only when a medical practitioner and facility policies determine it is safe and appropriate to discharge. The ambulatory surgical center must establish medical criteria for discharge which is consistent with prevailing professional standards.

<u>7-006.12E</u> Each ambulatory surgical center must, at least annually, provide surgeons performing surgery at the facility a report as to the number and rates of surgical infections in patients of the surgeons.

<u>7-006.13 Hemodialysis Services:</u> Each health clinic providing hemodialysis services must be licensed as a health clinic and must meet the regulations specified in 175 NAC 7-006.01 to 7-006.11 and 7-006.15. In addition, each health clinic must meet all requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services or its successor to participate in Medicare for hemodialysis services as defined in 42 CFR 405.2100 to 405.2163, attached to these regulations and incorporated by this reference.

<u>7-006.14 Labor and Delivery Services</u>: Each facility, not licensed as a hospital, that provides labor and delivery services must be licensed as a health clinic and must meet the regulations specified in 175 NAC 7-006.01 to 7-006.11; 7-006.15 and the following requirements:

<u>7-006.14A Care and Treatment:</u> Each facility must establish and implement written policies and procedures to ensure the safe delivery of care and treatment to patients. The policies and procedures must include, but are not limited to, the following:

- 1. Care and treatment during antepartum, intrapartum, postpartum, and newborn care:
- 2. Appropriate attire to be worn during labor and delivery;
- 3. The use of oxytocic drugs and administration of anesthetics, sedatives, analgesics, and other drugs, devices, and biologicals;
- 4. Visitation and attendance during the birth process; and
- 5. Method for identification of every newborn immediately after birth.

<u>7-006.14B Staff:</u> Each facility must have a sufficient number of qualified staff to meet the needs of patients. The staff must function in accordance with their scope of practice.

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- <u>7-006.14B1</u> Appropriate licensed health care professional staff must be on call at all times and available on-site at the facility within 30 minutes.
- <u>7-006.14B2</u> Nursing care during labor and delivery including care of the newborn must be supervised by a qualified registered nurse.
- <u>7-006.14B3</u> The direction and coordination of all medical aspects of the facility's policies must be by a physician designated by the governing authority.
- <u>7-006.14B4</u> At least one physician, certified nurse midwife, or registered nurse must be present at all times when a mother or newborn is in the facility.
- <u>7-006.14C</u> Emergency Equipment and Supplies: Each facility must have the necessary, drugs, devices, biologicals, equipment, and supplies immediately available for provision of care and treatment should an equipment emergency arise.
 - <u>7-006.14C1</u> The following emergency equipment must be available in the facility to provide care to both adults and newborns:
 - 1. Emergency call system;
 - 2. Oxvgen:
 - 3. Mechanical ventilation assistance equipment including airways and manual breathing bags;
 - 4. Cardiac defibrillator;
 - 5. Cardiac monitoring equipment;
 - 6. Tracheotomy sets;
 - 7. Laryngoscopes and endotracheal tubes; and
 - 8. Suction equipment.
- <u>7-006.14D Emergency Transfer:</u> Each facility must have a written agreement for emergency care with a hospital that provides obstetrical services or each medical practitioner practicing at the facility must have admitting privileges at a transferring hospital.
 - <u>7-006.14D1</u> Each facility must have the capability to transfer and transport the mother and/or newborn to the contract hospital(s) timely or have a written contract with an ambulance service that will assure timely response.
- <u>7-006.14E</u> Admission and Discharge: Each facility must establish and implement criteria for rejection, admission, discharge, and continuing care of patients which is clearly defined and made available for review to persons requesting such.
 - <u>7-006.14E1</u> Admissions to the facility must be restricted to low-risk patients who have received antepartum care in accordance with the facility's policies.
 - 7-006.14E2 Planned Caesarean Section procedures are prohibited.

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<u>7-006.14E3</u> Each mother and newborn must be discharged within 24 hours after admission, in a condition which will not endanger the well-being of either. If the condition of mother or newborn does not allow discharge within 24 hours, then transfer to a hospital must occur.

<u>7-006.14E4</u> Verbal and written instructions must be provided for observation and care of both the mother and newborn after discharge. The mother and newborn must be discharged in the care of the father or a responsible adult who will assist in their transport from the facility.

<u>7-006.14F</u> Records: Each facility must maintain a permanent admission and discharge patient index that includes, but is not limited to:

- 1. Full name of patient and identification number assigned by the facility;
- 2. Date and time of admission and discharge;
- 3. Name of admitting physician or certified nurse midwife;
- 4. Type of anesthesia;
- 5. Time of birth:
- 6. Gender of newborn; and
- 7. Disposition or place to which mother and newborn were discharged/ transferred.

7-006.14G All births must be reported in accordance with Neb. Rev. Stat. Section § 71-604.

<u>7-006.15 Environmental Services</u>: Each health clinic must provide a safe, clean, and comfortable environment for patients. Every detached building on the same premises used for care and treatment must comply with 175 NAC 7.

<u>7-006.15A</u> Housekeeping and Maintenance: The facility must provide the necessary housekeeping and maintenance to protect the health and safety of patients.

<u>7-006.15A1</u> The facility's buildings and grounds must be kept clean, safe and in good repair.

<u>7-006.15A2</u> All garbage and rubbish must be disposed of in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin. Garbage must be disposed in such a manner as to minimize the transmission of infectious diseases and minimize odor.

<u>7-006.15A3</u> The facility must maintain adequate lighting, environmental temperatures, and sound levels in all areas that are conducive to the care and treatment provided.

<u>7-006.15A4</u> The facility must maintain and equip the premises to prevent the entrance, harborage, or breeding of rodents, flies, and all other insects and vermin.

<u>7-006.15B</u> Equipment, Fixtures, and Furnishings: The facility must provide and maintain all equipment, fixtures, and furnishings clean, safe and in good repair.

<u>7-006.15B1</u> The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use.

<u>7-006.15C Linens:</u> The facility must maintain an adequate supply of linen necessary for the care and treatment of patients. Linen must be clean and in good repair.

<u>7-006.15C1</u> The facility must establish and implement procedures for the storage and handling of soiled and clean linens.

<u>7-006.15C2</u> When the facility provides laundry services, water temperatures to laundry equipment must exceed 160 degrees Fahrenheit or the laundry may be appropriately sanitized or disinfected by another acceptable method in accordance with manufacturer's instructions.

<u>7-006.15D Pets:</u> The health clinic must assure any facility owned pet does not negatively affect patients. The health clinic must have policies and procedures regarding pets that include:

- 1. An annual examination by a licensed veterinarian;
- 2. Vaccinations as recommended by the licensed veterinarian that include, at a minimum, current vaccination for rabies for dogs, cats, and ferrets;
- 3. Provision of pet care necessary to prevent the acquisition and spread of fleas, ticks and other parasites; and
- 4. Responsibility for care and supervision of the pet by health clinic staff.

<u>7-006.15E</u> Environmental Safety: The health clinic must be responsible for maintaining the environment in a manner that minimizes accidents.

<u>7-006.15E1</u> The facility must maintain the environment to protect the health and safety of patients by keeping surfaces smooth and free of sharp edges, mold, or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.

<u>7-006.15E2</u> The facility must maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.

<u>7-006.15E3</u> The facility must provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.

<u>7-006.15E3a</u> The facility must monitor and maintain water temperatures that accommodate comfort and preferences but not to exceed the following temperatures:

- 1. Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.
- 2. Water temperatures at bathing and therapy fixtures must not exceed 110 degrees Fahrenheit.

<u>7-006.15E4</u> The facility must establish and implement policies and procedures to ensure hazardous/poisonous materials are properly handled and stored to prevent accidental ingestion, inhalation, or consumption of the hazardous/poisonous materials by patients.

<u>7-006.15E5</u> The facility must restrict access to mechanical equipment which may pose a danger to patients.

<u>7-006.15F</u> Disaster Preparedness and Management: The health clinic must establish and implement <u>disaster preparedness plans and</u> procedures to ensure that patient care and treatment, safety, and well-being are <u>provided and</u> maintained during and following instances of natural <u>(tornado, flood, etc.)</u> and other disasters, disease outbreaks, or other similar situations <u>causing patients to remain at the clinic.</u> Such plans and procedures must address and delineate:

- 1. How the clinic will maintain the proper identification of each patient to ensure that care and treatment coincide with the patient's needs;
- 2. How the clinic will move patients to points of safety or provide other means of protection when all or part of the building is damaged or uninhabitable due to natural or other disaster. This must include:
 - a. Specification of the number and type of transportation vehicles that are to be used;
 - b. The method by which such vehicles will be accessed, whether owned and operated by the clinic or under contract with another entity. If transportation is to be provided by a contracted entity, the name, address, telephone number, and the type of vehicle to be used must be included in the disaster preparedness plan; and
 - c. The timeline for transportation of patients to points of safety;
- 3. How the clinic will provide food, water, medicine, medical supplies, and other necessary items for care in the event of a natural or other disaster:
- How the clinic will protect patients during the threat of exposure to the ingestion, absorption, or inhalation of hazardous substances or materials; and

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- 5. How the clinic will provide for the comfort, safety, and well-being of patients in the event of 24 or more consecutive hours of:
 - a. Electrical or gas outage;
 - b. Heating, cooling, or sewer system failure, or
 - c. Loss or contamination of water supply.

<u>7-006.15F1</u> The facility must establish plans to move patients to points of safety or provide other means of protection in case of fire, natural disasters, explosion, threat of ingestion, absorption or inhalation of hazardous materials.

<u>7-006.15F2</u> The facility must ensure that food, water, medicine and medical supplies, and other necessary items for care and treatment are available and obtainable from alternate sources.

<u>7-006.15F3</u> The facility must ensure that plans are in place to move and house patients in points of safety when the building or a portion of the building is damaged to the point it is uninhabitable. The damage may be due to fire, tornadoes, or other disasters.

<u>7-006.15F4</u> The facility must ensure that plans are in place to provide for the comfort, safety, and well being of patients in the event of electrical or gas outage, heating, cooling, or sewage systems failure, or loss or contamination of water supply.

<u>7-007 PHYSICAL PLANT STANDARDS:</u> All health clinics must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The physical plant standards for health clinics, which include support services, care and treatment areas, construction standards, building systems and waivers, are set forth below.

<u>7-007.01 Support Areas:</u> The health clinic may share the following support areas among detached structures, care and treatment areas, or with other licensed facilities.

<u>7-007.01A Dietary:</u> If food preparation is provided on site, the facility must dedicate space and equipment for the preparation of meals. Food service physical environment and equipment must comply with the Food Code.

<u>7-007.01B Laundry:</u> If the facility provides laundry services, the service may be provided by contract or on-site by the facility.

<u>7-007.01B1 Contract:</u> If contractual services are used, the facility must have areas for soiled linen awaiting pickup and separate areas for storage and distribution of clean linen.

<u>7-007.01B2</u> On-site: If on-site services are provided, the facility must have areas dedicated to laundry.

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<u>7-007.01B2a</u> In new construction, if the facility processes bulk laundry, the laundry must be divided into separate soiled (sort and washer areas) and clean (drying, folding, and mending areas) rooms with a separate soaking and hand washing sink <u>in</u> the laundry area.

<u>7-007.01B2b</u> Separate clean linen supply storage facilities must be conveniently located to care and treatment locations.

<u>7-007.01C</u> Diagnostic: If the facility provides radiology or laboratory services, the services must comply with the following:

<u>7-007.01C1</u> Imaging rooms must accommodate the operational and shielding requirements of the equipment installed, condition of the patient, and provide clear floor area adequate for the safety of staff and patients.

<u>7-007.01C2</u> Laboratory areas must provide for sample collection and protection, analyzing, testing, and storage. The facility must handle all potentially contagious and hazardous samples in a manner as to minimize transmission of infectious diseases.

<u>7-007.01D</u> Waste Processing: The health clinic must provide areas to collect, contain, process, and dispose of medical and general waste produced within the health clinic in such a manner as to prevent the attraction of rodents, flies, and all other insects and vermin, and to minimize the transmission of infectious diseases.

<u>7-007.01E Housekeeping Room:</u> The facility must have a room with a service sink and space for storage of supplies and housekeeping equipment.

<u>7-007.02 Care and Treatment Areas:</u> The health clinic must not share the following care and treatment areas among detached structures or with other facilities operated by another licensee. Care and treatment areas must comply with the following:

<u>7-007.02A</u> Staff Areas: Health clinics that provide nursing services must provide the following support areas for each distinct patient care and treatment areas.

<u>7-007.02A1</u> Control Point: The facility must have an area or areas for charting and patient records, and call and alarm annunciation systems.

<u>7-007.02A2 Medication Station:</u> The facility must have a medication station for storage and distribution of drugs and routine medications. Distribution may be done from a medicine preparation room or unit, from a self-contained medicine-dispensing unit, or by another system. If used, a medicine preparation room or unit must be under visual control of nursing staff and must contain a work counter, sink, refrigerator, and double-locked storage for controlled substances.

<u>7-007.02A3</u> Patient Facilities: The facility must have space for patient care, treatment, consultation, and waiting area.

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<u>7-007.02A4 Utility Area:</u> The facility must have a work area where clean materials are assembled. The work area must contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. A facility must have separate work rooms or holding rooms for soiled materials. A work room for soiled materials must contain a fixture for disposing wastes and a handwashing sink.

<u>7-007.02B</u> Equipment and Supplies: The health clinic must have services and space to distribute, maintain, clean, and sanitize durable medical instruments, equipment, and supplies required for the care and treatment performed in the facility.

<u>7-007.02B1 Durable Medical:</u> The facility must ensure that the durable medical equipment is tested and calibrated in accordance with the manufacturer's recommendations.

<u>7-007.02B2 Sterile Processing:</u> If sterile processing is completed onsite, the facility must have areas for decontamination and sterilizing of durable medical instruments and equipment.

<u>7-007.02B2a</u> The facility must provide separate sterile processing and waste processing areas.

<u>7-007.02B2b</u> In new construction and where provided, central sterile processing service area(s), must have separate soiled (sorting and decontamination) and clean (sterilizing and processing) rooms. The facility must have handwashing sinks in both clean and soiled rooms.

<u>7-007.02B3</u> Required Equipment: The facility must provide equipment adequate for meeting the care and treatment needs of patients.

<u>7-007.02B4</u> Equipment Storage: The facility must have space to store equipment, stretchers, wheelchairs, supplies, and linen out of the path of normal traffic.

<u>7-007.02C</u> Surgery: A health clinic providing surgical services must have at least one operating or procedure room and the following support areas. In new construction and facilities with more than two surgery rooms, the following support areas and central processing areas must be located in restricted access areas:

- Preoperative Patient Area: Preoperative patient area(s) must have sufficient space and equipment to accommodate both ambulatory and non-ambulatory patients. These areas must be under the direct visual control of the nursing staff.
- 2. Recovery Area: Recovery area(s) must contain a medication station,

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handwashing sink, charting area, provisions for bedpan cleaning, and equipment and supply storage space.

- 3. <u>Dressing Area:</u> The facility must have patient dressing and toilet rooms separate from staff gowning areas.
- 4. <u>Housekeeping Room:</u> The facility must have soiled utility and housekeeping areas exclusively for the surgical suite.

<u>7-007.02D</u> Emergency Care: A health clinic providing emergency services must have at least one procedure or treatment room. To support the provision of emergency care, the facility must have the following:

- 1. <u>Entrance:</u> A well marked, illuminated covered entrance at grade level for emergency vehicle and pedestrian access;
- 2. <u>Waiting Area:</u> Patient and visitor waiting area(s) that are in direct observation of the reception, triage, or control station, and have access to a public phone and drinking fountain;
- 3. <u>Storage:</u> Storage areas for general medical/surgical emergency supplies, medications, and equipment under staff control and out of the path of normal traffic; and
- 4. <u>Toilet Room:</u> A patient toilet room with handwashing sink which is convenient to the procedure or treatment room(s).

<u>7-007.02E</u> Rehabilitation: A facility providing rehabilitation services must have at least one treatment room or cubicle, an area for specialized treatment and care, handwashing sink(s), storage for equipment and supplies, call system, medication storage, and distribution, and areas to allow for patient toileting, dressing, and consultation.

<u>7-007.02F</u> Obstetrics: A facility providing obstetric services must have at least one patient room, space, and equipment to allow for care and treatment of both mother and infant, handwashing sink, storage for equipment and supplies, call and alarm annunciation systems, medication storage, and distribution, and convenient accommodations for patient toileting, dressing, and consultation.

<u>7-007.03 Construction Standards:</u> All health clinics must be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for such facilities are set forth below.

7-007.03A Codes and Guidelines

<u>7-007.03A1 New Construction:</u> New construction must comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

- 1. Building: Building Construction Act, Neb. Rev. Stat. §§ 71-6401 to 71-6407;
- 2. Plumbing: Plumbing Ordinance or Code, Neb. Rev. Stat. § 18-1915;
- 3. Electrical: State Electrical Act, Neb. Rev. Stat. §§ 81-2101 to 81-2143;
- 4. Elevators: Nebraska Elevator Code, Neb. Rev. Stat. § 48-418.12 and Department of Labor Regulations, 230 NAC 1;
- 5. Boiler: Boiler Inspection Act, Neb. Rev. Stat. §§ 48-719 to 48-743;
- 6. Accessibility: Nebraska Accessibility Requirements, State Fire Marshal Regulations, 156 NAC 1 to 12;
- 7. Design: Guidelines for Design and Construction of Hospitals and Health Care Facilities, Chapter 9, 2001 edition, published by the American Institute of Architects; and
- 8. Energy: Nebraska Energy Code, Neb. Rev. Stat. §§ 81-1608 to 81-1626, for construction initiated on or after July 1, 2005.
- 1. Building: The "Building Construction Act", Neb. Rev. Stat. Sections 71-6401 to 71-6407;
- 2. Plumbing: The "Plumbing Code", Neb. Rev. Stat. Section 18-1915:
- 3. Electrical: The "State Electrical Act", Neb. Rev. Stat. Sections 81-2101 to 81-2145;
- 4. Elevators: The "American National Standard Safety Code for Elevators and Escalators". 230 NAC 1:
- 5. Boiler: The "Boiler Inspection Act", Neb. Rev. Stat. Sections 48-719 to 48-743, and regulations promulgated thereunder, 220 NAC 1-28:
- 6. "Nebraska Accessibility Requirements" found at 156 NAC 1-12;
- 7. Guidelines: "Guidelines for Design and Construction of Hospital and Health Care Facilities", Chapter 9 of 1996-1997 edition published by the American Institute of Architectus Academy of Architecture for Health with assistance from the U.S. Department of Health and Human Services.

<u>7-007.03A2 All Facilities:</u> All facilities must comply with the following applicable codes and standards to provide a safe environment:

- 1. <u>Fire Codes:</u> The "Nebraska State Fire Code Regulations, State Fire Marshal, "found at 153 NAC 1; and
- 2. The Food Code, Neb. Rev. Stat. § 81-2,244.01, as published by the Nebraska Department of Agriculture, except for compliance and enforcement provisions.

<u>7-007.03A3</u> Existing and New Facilities: Existing and new facilities must comply with the physical plant standards contained in 175 NAC 7-007. The

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facility must maintain all building materials and structural components so that total loads imposed do not stress materials and components more than one and one half times the working stresses allowed in the building code for new buildings of similar structure, purpose, or location.

<u>7-007.03B Conflicts in Standards:</u> In situations where the referenced codes and guidelines conflict with 175 NAC 7, the adopted rules and regulations of the Department and the Nebraska State Fire Marshal will prevail.

<u>7-007.03C Interpretations:</u> All dimension, sizes, and quantities; noted herein will be determined by rounding fractions to the nearest whole number.

<u>7-007.03D</u> Floor Area: Floor area is the space with ceilings at least seven feet in height and does not include areas such as enclosed storage, toilets, and bathing rooms, corridors, and halls. The space beyond the first two feet of vestibules and alcoves less than five feet in width will not be included in the required floor area. In rooms with sloped ceilings, at least half of the ceiling must be at least seven feet in height with areas less than five feet in height, not included in the required floor area.

<u>7-007.03E</u> Bathing Rooms: If the facility provides a tub or shower for patient bathing, they must be equipped with hand grips or other assistive devices.

<u>7-007.03F</u> Toilet Rooms: The facility must provide at least one room with a toilet and sink for patient use.

<u>7-007.03G</u> Patient Rooms: The facility may provide rooms of the following types which allow for sleeping, afford privacy, provide access to furniture and belongings, and accommodate the care and treatment provided to the patient.

<u>7-007.03H Isolation Rooms:</u> The number and type of isolation rooms in a health clinic must be determined by the facility and must ensure a safe environment for patients.

<u>7-007.03l</u> Observation Areas: If the facility provides medical observation or behavior intervention methods, the facility must provide one or more appropriately equipped rooms for patients needing close supervision. Each room must:

- 1. Have appropriate temperature control, ventilation, and lighting;
- 2. Be void of unsafe wall or ceiling fixtures and sharp edges;
- 3. Have a way to observe the patient, such as an observation window or if necessary, flat wall mirrors so that all areas of the room are observable by staff from outside of the room;
- 4. Have a way to assure that the door cannot be held closed by the patient in the room which could deny staff immediate access to the room; and
- 5. Be equipped to minimize the potential of the patient's escape, injury, suicide, or hiding of restricted substances.

7-007.03J Bassinets: Each bassinet must have a minimum floor area of 40 square

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feet with at least 3 feet between bassinets.

<u>7-007.03K Cubicles</u>: Patient care and treatment cubicles must have a minimum floor area of 60 square feet with at least 3 feet between bedsides and adjacent side walls.

<u>7-007.03L</u> Examination Rooms: Each examination room must have a minimum floor area of 80 square feet and a minimum of 3 feet clear dimension around 3 sides of the examination table or chair.

<u>7-007.03M Treatment Rooms:</u> Treatment room for procedures performed under topical, local, or regional anesthesia without pre-operative sedation must have a minimum floor area of 120 square feet and a minimum of 10 feet clear dimension.

<u>7-007.03N</u> Procedure Rooms: Procedure rooms for invasive and minor surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs must have a minimum floor area of 200 square feet and a minimum of 14 feet clear dimension.

<u>7-007.030</u> Operating Rooms: Operating rooms for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions must have a minimum floor area of 300 square feet and a minimum of 16 feet clear dimension.

<u>7-007.03P Corridors:</u> The facility corridors must be wide enough to allow passage and be equipped as needed by the patients with safety and assistive devices to minimize injury. All stairways and ramps must have handrails.

<u>7-007.03Q</u> <u>Doors:</u> The health clinic doors must be wide enough to allow passage and be equipped for privacy, safety, and with assistive devices to minimize patient injury.

<u>7-007.03Q1</u> All toilet and bathing room doors must provide privacy yet not create seclusion or prohibit staff access for routine or emergency care.

<u>7-007.03Q2</u> In new construction all toilet and bathing rooms used by patients with less than 50 square feet of clear floor area must not have doors that solely swing inward.

<u>7-007.03Q3</u> Doors may prevent escape and create seclusion where therapeutically required, such as emergency protective custody, detoxification and psychiatric locations.

<u>7-007.03R</u> Outdoor Areas: Any outdoor area for patient usage provided by the facility must be equipped and situated to allow for patient safety and abilities.

<u>7-007.03S</u> Handwashing Sinks: The facility must provide a handwashing sink equipped with towels and soap dispenser in all examination, treatment, isolation,

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and procedure rooms; available to every four care and treatment cubicle locations; and one scrub sink near the entrance of each operating room.

<u>7-007.03T Privacy:</u> In multiple bed patient care and treatment rooms, visual privacy, and window curtains must be provided for each patient. In new construction and new facilities, the curtain layout must totally surround each care and treatment location which will not restrict access to the entrance to the room, lavatory, toilet, or enclosed storage facilities.

<u>7-007.03U</u> Finishes: Room finishes in care and treatment areas must comply with the following:

- Washable room finishes provided in procedure rooms, existing isolation rooms, sterile processing rooms, workroom, laundry, and foodpreparation areas must have smooth, non-adsorptive, surfaces; which are not physically affected by routine housekeeping cleaning solutions and methods. Acoustic lay-in ceilings, if used, must be non-perforated washable.
- Scrubbable room finishes provided in operating rooms and new isolation rooms must have smooth, non-adsorptive, non-perforated surfaces that are not physically affected by harsh germicidal cleaning solutions and methods.

<u>7-007.04 Building Systems:</u> Health clinics must have building systems that are designed, installed and operated in such a manner as to provide for the safety, comfort, and well being of the patient.

<u>7-007.04A</u> Water and Sewer Systems: The facility must have and maintain an accessible, adequate, safe, and potable supply of water. Where an authorized public water supply of satisfactory quantity, quality, and pressure is available, the facility must be connected to it and its supply used exclusively.

<u>7-007.04A1</u> The collection, treatment, storage, and distribution potable water system of a facility that regularly services 25 or more individuals must be constructed, maintained, and operated in accordance with all provisions of the Nebraska Safe Drinking Water Act and Title 179 Regulations Governing Public Water Systems.

<u>7-007.04A2</u> The collection, treatment, storage and distribution potable water system of a facility that serves less than 25 individuals on a regular basis must be maintained and operated as if it were a public water system in accordance with the Regulations Governing Public Water Systems, 179 NAC 2-002, 3 and 4. The facilities must report to the Department the result of all tests that indicate the water is in violation of the standards set out in 179 NAC 2-002 or 3. The facilities must construct all water wells in accordance with 178 NAC 12, Water Well Construction, Pump Installation, and Water Well Decommissioning Standards. Rules and Regulations Governing a Private

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Water Well.

<u>7-007.04A3</u> The water distribution system must be protected with anti-siphon devices, and air-gaps to prevent potable water system and equipment contamination.

<u>7-007.04A4</u> Continuously circulated filtered and treated water systems must be provided as required for the care and treatment equipment used in the health clinic.

<u>7-007.04A5</u> The facility must maintain a sanitary and functioning sewage system.

<u>7-007.04B Hot Water System:</u> The facility must maintain hot and cold water to all hand washing and bathing locations. The hot water system must have the capacity to provide continuous hot water at temperatures as required by 175 NAC 7.

<u>7-007.04C</u> Heating and Cooling Systems: The facility must provide a heating and air conditioning system for the comfort of the patient and capable of maintaining the temperature in patient care and treatment areas as follows:

<u>7-007.04C1</u> In existing and new facilities, the systems must be capable of producing a temperature of at least 70 degrees Fahrenheit during heating conditions and a temperature that does not exceed 85 degrees Fahrenheit during cooling conditions.

<u>7-007.04C2</u> In new construction the systems must be capable of producing a temperature of at least 75 degrees Fahrenheit during heating conditions and a temperature that does not exceed 80 degrees Fahrenheit during cooling conditions.

<u>7-007.04C3</u> In new construction, central air distribution, and return systems must have the following percent dust rated filters:

- 1. General areas: 30 +%; and
- 2. Procedure and operating rooms: 90 +%.

<u>7-007.04C4</u> Surgical areas must have heating and cooling systems that are capable of producing room temperatures at a range between 68 and 73 degrees Fahrenheit and humidity at a range between 30 and 60% relative humidity.

<u>7-007.04C5</u> Airflow must move from clean to soiled locations. In new construction, air movement must be designed to reduce the potential of contamination of clean areas.

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<u>7-007.04C6</u> Floors in operating, procedure, and other locations subject to wet cleaning methods or body fluids must not have openings to the heating and cooling system.

<u>7-007.04D Ventilation System:</u> All facilities must provide exhaust and clean air to prevent the concentrations of contaminants which impair health or cause discomfort to patients and employees.

7-007.04D1 Existing and new facilities must have adequate ventilation.

<u>7-007.04D2</u> New construction must provide mechanical exhaust ventilation system for windowless toilets, baths, laundry rooms, housekeeping rooms, kitchens, and similar rooms at ten air changes per hour.

<u>7-007.04D3</u> New construction must provide mechanical ventilation system(s) capable of providing air changes per hour (hereafter ACH) as follows:

Care and treatment areas: 5 ACH;

2. Procedure and respiratory isolation areas: 5 15 ACH; and

3. Operating rooms: 20 ACH.

<u>7-007.04E Electrical System:</u> The facility must have an electrical system that has sufficient capacity to maintain the care and treatment services that are provided and that properly grounds care and treatment areas.

<u>7-007.04E1</u> New construction and new facilities must have ground fault circuit interrupters protected outlets in wet areas and within 6 feet of sinks.

<u>7-007.04E2</u> All facilities must provide the minimum average illumination levels as follows:

1.	General purpose areas:	5 foot candles;
2.	General corridors:	10 foot candles;
3.	Personal care and dining areas:	20 foot candles;
4.	Reading and activity areas:	30 foot candles;
5.	Food preparation areas:	40 foot candles;
6.	Hazardous work surfaces:	50 foot candles;
7.	Care and treatment locations:	70 foot candles;
8.	Examination task lighting:	100 foot candles;
9.	Procedure task lighting:	200 foot candles; and
10.	Surgery task lighting:	1000 foot candles.

<u>7-007.04F Essential Power System:</u> Facilities must have an emergency power generator for all care and treatment locations which involve general anesthetics or electrical life support equipment, and in emergency procedure and treatment rooms.

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<u>7-007.04F1</u> Existing and new facilities must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, and nurse call systems.

<u>7-007.04F2</u> New construction must maintain emergency power for essential care and treatment equipment and lighting, medical gas systems, ventilation and heating systems, and nurse call systems.

<u>7-007.04F3</u> Facilities with electrical life support equipment must maintain essential power systems and must have on-site fuel source. The minimum fuel source capacity must allow for non-interrupted system operation.

<u>7-007.04G Call Systems:</u> Call system(s) must be operable from patient procedure and operating rooms, recovery bed, and toilet areas. The system must transmit a receivable (visual, audible, tactile, or other) signal to on-duty staff which readily notifies and directs the staff to the location where the call was activated.

<u>7-007.04G1</u> In new construction, the call system must have a dedicated emergency call device which allows activation by a patient from treatment rooms and cubicles, and toilet and bathing fixtures.

<u>7-007.04G2</u> In new construction, in locations where patients are unable to activate the call, a dedicated staff assist call device must promptly summon other staff for assistance.

<u>7-007.04G3</u> Existing health clinics, except ambulatory surgical centers, that do not have a nurse call system are not required to provide a nurse call system.

<u>7-007.04H Medical Gas System:</u> The facility must safely provide medical gas and vacuum by means of portable equipment or building systems as required by patients receiving care and treatment.

<u>7-007.04H1</u> The installation, testing, and certification of nonflammable medical gas, clinical vacuum, and air systems must comply with the requirements of 153 NAC 1 Nebraska State Fire Code Regulations.

<u>7-007.04H2</u> The facility must identify portable and system components, and periodically test and approve all medical gas piping, alarms, valves, and equipment for patient care and treatment. The facility must document such approvals for review and reference.

<u>7-007.05 Waivers:</u> The Department may waive any provision of 175 NAC 7 relating to construction or physical plant requirements of a health clinic upon proof by the licensee satisfactory to the Department (a) that such waiver would not unduly jeopardize the health, safety, or welfare of the persons served by the facility, (b) that such provision would create an unreasonable hardship for the facility, and (c) that such waiver would not cause the State of Nebraska to fail to comply with any applicable requirements of

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Medicare or Medicaid so as to make the state ineligible for the receipt of all funds to which it might otherwise be entitled.

<u>7-007.05A</u> Unreasonable Hardship: In evaluating the issue of unreasonable hardship, the Department must will consider the following:

- 1. The estimated cost of the modification or installation;
- 2. The extent and duration of the disruption of the normal use of areas used by persons residing in or served by the facility resulting from construction work:
- 3. The estimated period over which the cost would be recovered through reduced insurance premiums and increase reimbursement related to costs:
- 4. The availability of financing; and
- 5. The remaining useful life of the building.

<u>7-007.05B Waiver Terms and Conditions:</u> Any such waiver may be granted under the terms and conditions and for such period of time as are applicable and appropriate to the waiver. Terms and conditions and period of waiver include but are not limited to:

- 1. Waivers that are granted to meet the special needs of a patient remain in effect as long as required by the patient;
- 2. Waivers may be granted for a period of time that ends at the time the conditions of approval no longer exist;
- 3. Waivers may be granted to permit a facility time to come into compliance with the physical plant standards for a period of one year. Upon submission of proof of ongoing progress, the waiver may be continued for an additional year; and
- 4. An applicant or licensee must submit a request for waiver of any construction or physical plant requirements set forth in 175 NAC 7. An applicant for a waiver may construct a request for a waiver form or obtain a form from the Department.

<u>7-007.05C</u> Denial of Waiver: If the Department denies a health clinic's request for waiver, the facility may request an administrative hearing as provided in the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA.

7-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

7-008.01 Grounds for Denial, Refusal to Renew or Disciplinary Action:

<u>7-008.01A</u> The Department may deny or refuse to renew a health clinic license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 7-005;

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- 2. Having had a license revoked within the two-year period preceding an application; or
- 3. Any of the grounds specified in 175 NAC 7-008.01B.

<u>7-008.01B</u> The Department may take disciplinary action against a health clinic license for any of the following grounds:

- 1. Violation of any of the provisions of the Health Care Facility Licensure Act, or 175 NAC 7;
- 2. Committing or permitting, aiding, or abetting the commission of any unlawful act;
- 3. Conduct or practices detrimental to the health or safety of a health clinic patient or employee;
- 4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health clinic;
- 5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the health clinic for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of such departments;
- 6. Discrimination or retaliation against a health clinic patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
- 7. Discrimination or retaliation against a health clinic patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
- Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the health clinic for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
- 9. Violation of the Emergency Box Drug Act;
- 10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. Section § 71-168.02;

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- 11. Violation of the Medication Aide Act; or
- 12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. Sections §§ 28-372 and 28-711.

7-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action:

<u>7-008.02A</u> If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department <u>must will</u> send a notice to the applicant or licensee, by certified mail to the last address shown on its records The notice <u>must will</u> state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

<u>7-008.02B</u> The denial, refusal to renew, or disciplinary action must will become final 15 days after the mailing of the notice unless the applicant or licensee, within such 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

7-008.02C Informal Conference

<u>7-008.02C1</u> At the request of the applicant or licensee, the Department <u>must will</u> hold an informal conference within 30 days of the receipt of the request. The conference <u>must will</u> be held in person or by other means, at the request of the applicant or licensee.

If the pending action is based on an inspection, the Department's representative at the conference must will not be the individual who did the inspection.

<u>7-008.02C2</u> Within 20 working days of the conference, the Department representative <u>must will</u> state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative <u>must will</u> send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.

<u>7-008.02C3</u> If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department <u>must will</u> remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.

<u>7-008.02C4</u> If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing within five working days after receipt of the statement.

7-008.02D Administrative Hearing

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<u>7-008.02D1</u> When an applicant or a licensee contests the notice and request a hearing, the Department must will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by <u>Neb. Rev. Stat. Sections</u> §§ 33-139 and 33-139.01.

<u>7-008.02D2</u> On the basis of evidence presented at the hearing, the Director must will affirm, modify, or set aside the determination. The Director's decision must will:

- 1. Be in writing;
- Be sent by registered or certified mail to the applicant or licensee; and
- 3. Become final 30 days after mailing unless the applicant or licensee, within such 30-day period, appeals the decision.

<u>7-008.02D3</u> An applicant or a licensee's appeal of the Director's decision must be in accordance with the APA.

7-008.03 Types of Disciplinary Action

<u>7-008.03A</u> The Department may impose any one or a combination of the following types of disciplinary action against the license of a health clinic:

- 1. A fine not to exceed \$10,000 per violation:
- 2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
- A period of probation not to exceed two years during which the facility or service may continue to operate under terms and conditions fixed by the order of probation;
- 4. A period of suspension not to exceed three years during which the facility or service may not operate; and
- 5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

<u>7-008.03B</u> In determining the type of disciplinary action to impose, the Department must will consider:

- 1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
- 2. The severity of the actual or potential harm;
- 3. The extent to which the provisions of applicable statutes, rules, and regulations were violated:
- 4. The reasonableness of the diligence exercised by the health clinic in identifying or correcting the violation;
- 5. Any previous violations committed by the health clinic; and

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6. The financial benefit to the facility of committing or continuing the violation.

<u>7-008.03C</u> If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 7-008.03A.

<u>7-008.03D</u> Temporary Suspension or Temporary Limitation: If the Department determines that patients of the health clinic are in imminent danger of death or serious physical harm, the Director may:

- 1. Temporarily suspend or temporarily limit the health clinic license, effective when the order is served upon the health clinic. If the licensee is not involved in the daily operation of the health clinic, the Department must will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent;
- 2. Order the immediate removal of patients; or
- 3. Order the temporary closure of the health clinic pending further action by the Department.

The Department <u>must will</u> simultaneously institute proceedings for revocation, suspension, or limitation of the license, and <u>must will</u> conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

<u>7-008.03D1</u> The Department must will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by <u>Neb.</u> Rev. Stat. Sections §§ 33-139 and 33-139.01.

<u>7-008.03D2</u> If a written request for continuance of the hearing is made by the licensee, the Department <u>must will</u> grant a continuance, which may not exceed 30 days.

<u>7-008.03D3</u> On the basis of evidence presented at the hearing, the Director must will:

- 1. Order the revocation, suspension, or limitation of the license; or
- 2. Set aside the temporary suspension or temporary limitation.

If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

<u>7-008.03D4</u> Any appeal of the Department's decision after hearing must be in accordance with the APA.

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7-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

7-008.04A Reinstatement at the End of Probation or Suspension

<u>7-008.04A1</u> Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

<u>7-008.04A2</u> Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

- 1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 7-003.02;
- 2. Payment of the renewal fee as specified in 175 NAC 7-004.09; and
- 3. Successful completion of an inspection.

The Department <u>must will</u> reinstate the license when it finds, based on an inspection as provided for in 175 NAC 7-005, that the health clinic is in compliance with the operation, care, treatment, and physical plant requirements of 175 NAC 7-006 and 7-007.

7-008.04B Reinstatement Prior to Completion of Probation or Suspension

<u>7-008.04B1</u> Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

- 1. Submit a petition to the Department stating:
 - a. The reasons why the license should be reinstated prior to the probation completion date; and
 - b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and
- 2. Successfully complete any inspection that the Department determines necessary.

<u>7-008.04B2</u> Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

- 1. Submit a petition to the Department stating:
 - a. The reasons why the license should be reinstated prior to the suspension completion date; and

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- b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension.
- 2. Submit a written renewal application to the Department as specified in 175 NAC 7-003.02;
- 3. Pay the renewal fee as specified in 175 NAC 7-004.09; and
- 4. Successfully complete an inspection.

<u>7-008.04B3</u> The Director must will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

- 1. Grant full reinstatement of the license:
- 2. Modify the probation or suspension; or
- 3. Deny the petition for reinstatement.

<u>7-008.04B4</u> The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing must will be held according to rules and regulations of the Department for administrative hearings in contested cases.

<u>7-008.04C</u> Re-Licensure After Revocation: A health clinic license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

<u>7-008.04C1</u> A health clinic seeking re-licensure must apply for an initial license and meet the requirements for initial licensure in 175 NAC 7-003.01.

<u>7-008.04C2</u> The Department <u>must will</u> process the application for re-licensure in the same manner as specified in 175 NAC 7-003.01.